IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS LLC, PF PRISM C.V., PBG PUERTO RICO LLC and PF PRISM IMB B.V.)))
Plaintiffs,)
v. SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC.,) C.A. No. 16-1305 (RGA)) CONSOLIDATED)) REDACTED PUBLIC VERSION
Defendants.	Original Filing Date: October 18, 2019 Redacted Filing Date: October 25, 2019

PROPOSED PRETRIAL ORDER

This matter comes before the Court at a final pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure and Local Rule 16.3. Plaintiffs Wyeth LLC, Wyeth Pharmaceuticals LLC, PF Prism C.V., PBG Puerto Rico LLC, and PF PRISM IMB B.V. (collectively "Pfizer" or "Plaintiffs"), defendants Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively "Sun" or "Defendants"), by their undersigned counsel, submit this proposed Joint Pretrial Order pursuant to D. Del. L.R. 16.3 governing the consolidated bench trial of Civil Action Nos. 16-1305 and 17-1362 (collectively, "the Actions"), which is currently scheduled to begin on November 4, 2019.

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I. NATURE OF THE CASE

A. Plaintiffs' Complaint

- 1. This is a consolidated action for patent infringement brought pursuant to the Hatch-Waxman Act, codified as amended at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), concerning Pfizer's drug product BOSULIF® (100 mg, 400 mg, and 500 mg bosutinib tablets), approved by the United States Food and Drug Administration ("FDA"), and indicated for the treatment of adult patients with (i) newly-diagnosed chronic phase ("CP") Philadelphia chromosome-positive chronic myelogenous leukemia ("Ph+ CML"), or (ii) chronic phase, accelerated phase ("AP"), or blast phase ("BP") Ph+ CML with resistance or intolerance to prior therapy.
- 2. Plaintiffs filed suit against Sun for infringement of United States Patent Nos. 7,417,148 (the "'148 patent") (PTX-016; JTX-001), 7,767,678 (the "'678 patent) (PTX-083; JTX-002), and 7,919,625 (the "'625 patent') (PTX-150; JTX-003) (collectively, the "Patents-in-Suit") based on Sun's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the FDA to market generic bosutinib tablets prior to expiration of the Patents-in-Suit. (Plaintiffs' Second Amended Complaint, C.A. No. 16-1305, D.I. 60, at 1-2; Plaintiffs' Complaint, C.A. No. 17-1362, D.I. 1, at 1). Sun filed declaratory judgment counterclaims against Plaintiffs alleging invalidity and non-infringement of the Patents-in-Suit. (Sun's Answer and Counterclaims to Second Amended Complaint, C.A. No. 16-1305, D.I. 64, at 14-19; Sun's Answer and Counterclaims to Complaint, C.A. No. 17-1362, D.I. 7, at 9-16).

B. Asserted Claims

3. Plaintiffs allege that Sun infringed each of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e)(2) by submission of ANDA No. 209577 ("Sun's ANDA") seeking approval to market generic bosutinib tablets prior to expiration of the Patents-in-Suit. Plaintiffs also allege

that Sun will directly infringe the '625 patent and '678 patent if the FDA were to approve and Sun were to manufacture, use, offer for sale, sell, and/or import its generic bosutinib tablets prior to expiration of the patents. (Plaintiffs' Second Amended Complaint, C.A. No. 16-1305, D.I. 60, at 17-18; Plaintiffs' Complaint, C.A. No. 17-1362, D.I. 1, at 8-9). Plaintiffs further allege that Sun will induce and/or contribute to infringement of the '148 patent if the FDA were to approve and Sun were to sell its generic bosutinib tablets with Sun's proposed labeling and prescribing information prior to the expiration of the '148 patent. (Plaintiffs' Second Amended Complaint, C.A. No. 16-1305, D.I. 60, at 17-19; Plaintiffs' Complaint, C.A. No. 17-1362, D.I. 1, at 7-9).

- 4. Plaintiffs are presently asserting infringement of the following claims against Sun:
 - '148 patent: 7
 - '678 patent: 2 and 3
 - '625 patent: 1
- 5. Plaintiffs request that the Court enter: (a) a judgment that Sun's submission of ANDA No. 209577 was an act of infringement and that Sun's making, using, offering to sell, selling, or importing generic bosutinib tablets prior to the expiration of the Patents-in-Suit will infringe, actively induce infringement, and/or contribute to the infringement of the Patents-in-Suit; (b) a judgment that the effective date of any FDA approval for Sun to make, use offer for sale, sell, market, distribute, or import generic bosutinib tablets be no earlier than the date on which the Patents-in-Suit expire, or any later expiration of exclusivity to which Plaintiffs are or become entitled; (c) a permanent injunction enjoining Sun, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing generic bosutinib tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the Patents-

in-Suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled; (d) a judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys' fees for bringing and prosecuting this action; (e) an award of Plaintiffs' costs and expenses in this action; and (f) such further and additional relief as this Court deems just and proper. (Plaintiffs' Second Amended Complaint, C.A. 16-1305, D.I. 60, at 19-20; Plaintiffs' Complaint, C.A. 17-1362, D.I. 1, at 9-10).

C. Defendants' Answers, Defenses and Counterclaims

- 6. Sun Pharmaceutical Industries Limited ("SPIL") filed ANDA No. 209577 seeking approval from FDA for a generic bosutinib product prior to the expiration of the '148, '625 and '678 patents.
- 7. Sun Pharmaceutical Industries, Inc. ("SPII") is SPIL's U.S. Agent for the purposes of ANDA No. 209577.
- 8. Sun denies all claims of infringement by Plaintiffs relating to the '148, '625 and '678 patents.
- 9. Sun also alleges all claims of the '148, '625 and '678 are invalid or unenforceable.
- 10. It is Sun's position the filing of Sun's ANDA No. 209577 has not infringed and does not infringe, any valid and enforceable claim of the '148 patent, either literally or under the doctrine of equivalents.
- 11. Sun further states the manufacture, use, sale and/or offer for sale of Sun's ANDA Product has not infringed, does not infringe and would not, if marketed, infringe any valid and enforceable claim of the '148 patent.
- 12. It is Sun's position it has not and will not induce infringement of, and/or contribute to the infringement of, any valid and/or enforceable claim of the '148 patent.

- 13. Sun also alleges the claims of the '148 patent are invalid for failing to satisfy one or more of the requirements for patentability according to at least, 35 U.S.C. §§ 102, 103 and/or 112.
- 14. It is Sun's position the filing of Sun's ANDA No. 209577 has not infringed and does not infringe, any valid and enforceable claim of the '625 patent, either literally or under the doctrine of equivalents.
- 15. Sun further states the manufacture, use, sale and/or offer for sale of Sun's ANDA Product has not infringed, does not infringe and would not, if marketed, infringe any valid and enforceable claim of the '625 patent.
- 16. It is Sun's position it has not and will not induce infringement of, and/or contribute to the infringement of, any valid and/or enforceable claim of the '625 patent.
- 17. Sun also alleges the claims of the '625 patent are invalid for failing to satisfy one or more of the requirements for patentability according to at least, 35 U.S.C. §§ 102, 103 and/or 112.
- 18. It is Sun's position the filing of Sun's ANDA No. 209577 has not infringed and does not infringe, any valid and enforceable claim of the '678 patent, either literally or under the doctrine of equivalents.
- 19. Sun further states the manufacture, use, sale and/or offer for sale of Sun's ANDA Product has not infringed, does not infringe and would not, if marketed, infringe any valid and enforceable claim of the '678 patent.
- 20. It is Sun's position it has not and will not induce infringement of, and/or contribute to the infringement of, any valid and/or enforceable claim of the '678 patent.

- 21. Sun also alleges the claims of the '678 patent are invalid for failing to satisfy one or more of the requirements for patentability according to at least, 35 U.S.C. §§ 102, 103 and/or 112.
- 22. Sun has also asserted counterclaims for declaratory judgment of non-infringement of the '148, '625 and '678 patents .
- 23. Sun has asserted additional counterclaims for declaratory judgment of invalidity of the '148, '625 and '678 patents.
- 24. Sun requests the Court deny Plaintiffs all requests for relief and requests judgment be entered declaring Sun has not infringed, does not and will not infringe, and does not and will not induce infringement of any valid and enforceable claim of the '148, '625 and '678 patents and that Sun has the lawful right to obtain FDA approval of ANDA No. 209577 for its bosutinib tablets and that Sun has a lawful right to manufacture, import, use, sell and/or of offer to sell its bosutinib tablets in the United States once approved by FDA.
- 25. Sun further requests judgment be entered declaring the claims of the '148, '625 and '678 patents invalid.
- 26. Sun further requests judgment be entered declaring this case exceptional, as contemplated by 35 U.S.C. §285, and award Sun reasonable attorneys' fees, costs and expenses accrued in this action as well as such further and additional relief as this Court deems just and proper.

D. Plaintiffs' Answers to Counterclaims

27. Plaintiffs have denied all counterclaims asserted by Sun of non-infringement and invalidity of the Patents-in-Suit. (Plaintiffs' Answer to Sun's Counterclaims, C.A. No. 16-1305, D.I. 68, at 4; Plaintiffs' Answer to Sun's Counterclaims, C.A. No. 17-1362, D.I. 10, at 3-5).

E. Consolidation

28. On November 15, 2017, the court consolidated the Actions under the above-captioned lead case, C.A. 16-1305. (C.A. 16-1305, D.I. 56; C.A. 17-1362, D.I. 13).

F. Claim Construction

29. The Court held a claim construction hearing and issued a *Markman* Order on June 27, 2018. (C.A. 16-1305, D.I. 98). In addition, the parties agreed to the constructions of certain terms. (Parties' Joint Claim Construction Brief, C.A. 16-1305, D.I. 91, at 3-4).

G. Pending Motions

- 30. On August 30, 2019, Plaintiffs filed a *Daubert* motion seeking to exclude testimony from Defendants' expert Dr. Lindsley with respect to Pfizer's diligence in reducing to practice the inventions of the '148 patent and the '625 patent. (C.A. 16-1305, D.I. 226).
- 31. On August 30, 2019, Sun filed a *Daubert* motion seeking to exclude all opinions and testimony from Plaintiffs' expert Dr. Trout. (C.A. 16-1305, D.I. 227).

II. JURISDICTION

- 32. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 33. Plaintiffs allege that the Court has personal jurisdiction over Sun. Defendants do not dispute the Court's exercise of personal jurisdiction for the Actions.
- 34. Plaintiffs allege that venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b). Defendants do not dispute venue in this Court for the Actions.

III. FACTS

A. <u>Uncontested Facts</u>

35. The parties' Joint Statement of Uncontested Facts is attached as **Exhibit 1**. The facts are not disputed, or have been agreed to or stipulated by the parties. These facts should become part of the evidentiary record in the case.

B. <u>Contested Facts</u>

- 36. Plaintiffs' Issues of Facts to be Litigated at trial are attached as **Exhibit 2**.
- 37. Defendants' Issues of Facts to be Litigated at trial are attached as **Exhibit 3**.
- 38. If this Court determines that any issue identified in the statements of issues of fact is more properly considered an issue of law, it should be so considered.

IV. ISSUES OF LAW

39. Plaintiffs' Statement of Issues of Law that Remain to be Litigated is attached as **Exhibit 4**.

40. Defendants' Statement of Issues of Law that Remain to be Litigated is attached as **Exhibit 5**.

41. If this Court determines that any issue identified in the statements of issues of law is more properly considered an issue of fact, it should be so considered.

V. WITNESSES

42. Presentation of evidence will follow the burden of proof. First, Plaintiffs will present their case-in-chief on infringement. Second, Defendants will present their response on infringement. Third, Plaintiffs will present their rebuttal on infringement. Fourth, Defendants will present their case-in-chief on invalidity. Fifth, Plaintiffs will present their response on invalidity. Sixth, Defendants will present their rebuttal on invalidity.

- 43. In the absence of an alternative agreement between the parties, fact witnesses shall be sequestered.
- 44. Unless otherwise agreed between the parties, the parties will identify witnesses expected to testify by 7:00 p.m. two calendar days before the direct examination will take place.
- 45. The parties will confer nightly to update opposing counsel as to the expected day that the party intends to complete its presentation of evidence.

A. List of Witnesses to be Called

- 46. Plaintiffs' List of Witnesses to be Called Live or By Deposition is attached as **Exhibit 6**. Exhibit 6 further identifies the subject matter on which Plaintiffs will ask the Court to recognize each expert witness's expertise. No deviations as to the described subject matter will be permitted without prior approval of all parties or the Court, on good cause shown.
- 47. Defendants' List of Witnesses to be Called Live or By Deposition is attached as **Exhibit 7**. Exhibit 7 further identifies the subject matter on which Defendants will ask the Court to recognize each expert witness's expertise. No deviations as to the described subject matter will be permitted without prior approval of all parties or the Court, on good cause shown.
- 48. To the extent a fact witness becomes unavailable for trial (as that is defined by the Federal Rules), each party reserves the right to call that witness by deposition, as set forth below in this pretrial order.
- 49. The parties further reserve the right to call: (1) one or more additional witnesses whose testimony is necessary to establish authenticity or admissibility of any trial exhibit, if that evidentiary status of the exhibit is challenged by an opposing party; (2) additional witnesses to respond to any issues raised by the Court's pretrial or trial rulings; (3) any witness live for impeachment purposes to the extent permitted by applicable rules; and (4) any witness who appears on the other party's witness list.

50. Any witness not listed or provided for in accordance with this Section will be precluded from testifying, absent good cause shown.

B. Testimony by Deposition

- 51. The deposition testimony Plaintiffs may offer into evidence is identified in **Exhibit 8**.
- 52. The deposition testimony Defendants may offer into evidence is identified in **Exhibit 9**.
- 53. This pretrial order contains the entire universe of deposition designations, counter-designations, and objections to admission of deposition testimony; none of the foregoing shall be supplemented without approval of all parties or leave of the Court, on good cause shown. A party's decision not to introduce some or all of the testimony of a witness designated by that party herein shall not be commented upon by the other party at trial. Either party is entitled to use the deposition testimony as designated herein by the other party.
- 54. With respect to those witnesses whom the parties have identified in Exhibits 6 and 7 that will be called to testify live at trial, no deposition designations or counter-designations are required. Should a fact witness identified in Exhibits 6 and 7 as testifying live at trial become unavailable, as that term is defined in the Federal Rules of Civil Procedure and Federal Rules of Evidence, the parties may designate specific pages and lines of transcript that they intend to read or play in lieu of the witness's appearance upon reasonable notice.
- 55. For deposition testimony provided to the Court, the parties providing the designated testimony shall serve the other parties with the transcript pages and line numbers of the deposition testimony they intend to introduce by 7:00 p.m. two calendar days before such testimony is to be introduced. The opposing parties will identify any objections to the designated deposition testimony and any specific pages and lines from that deposition to counter-designate

by 7:00 p.m. the next day (one calendar day before such testimony is to be introduced), and identify the manner in which the deposition will be used. Anticipated objections are listed in Exhibits 8 and 9, and the parties shall not be permitted to add or assert different objections to deposition testimony designated or counter-designated in Exhibits 8 and 9. The parties shall meet and confer to resolve any objections to designated testimony by 10:00 p.m. that same day (one calendar day before such testimony is to be introduced).

- 56. If there are objections that remain to be resolved, the party calling the witness by deposition shall submit, on behalf of all parties: (i) a copy of the entire deposition testimony of the witness at issue, clearly highlighting the designations, counter-designations, and pending objections; and (ii) a cover letter clearly identifying the pending objections as well as a brief indication (*i.e.*, no more than one sentence per objection) of the basis for the objection and the offering party's response to it. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of the deposition testimony or waiver of objection to the use of the deposition testimony.
- 57. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is viewed at trial.
- 58. When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with two copies of the transcript of the designations and counter-designations that will be played. The parties will be charged for all time that elapses from the time the witness is called until the next witness is called, according to the proportions to be provided by the parties.
- 59. When deposition designation excerpts are introduced, all admissible deposition counter-designations excerpts will be introduced simultaneously in the sequence in which the

testimony was originally given. The specific portions of the deposition shall be played in page order. If an exhibit is referenced in a deposition designation, the exhibit is admitted into evidence if it is included on the offering party's trial exhibit list and is not otherwise objected to, or is included on the joint trial exhibit list.

C. <u>Impeachment with Prior Inconsistent Statements</u>

60. Pursuant to Fed. R. Evid. 613, deposition and other testimony or statements not specifically identified on a party's deposition designation list or exhibit list may be used at trial only for the purpose of impeachment, if otherwise competent for such purpose. The Court will rule at trial on any objections based on lack of completeness and/or lack of consistency.

D. Objections to Expert Testimony

61. The parties request that the Court rule at trial on any objections to expert testimony as beyond the scope of expert disclosures. Before each expert takes the stand, the parties shall provide copies of that expert's report(s) and deposition testimony to the Court. However, unless expressly moved and accepted into evidence, the expert report(s) and deposition testimony shall be used only for the purpose of ruling on objections to expert testimony offered at trial.

VI. EXHIBITS

A. Trial Exhibits

62. Plaintiffs' list of exhibits that they may offer at trial, except demonstrative exhibits and exhibits to be used solely for impeachment, and Defendants' objections to Plaintiffs' exhibits, are attached as **Exhibit 10**. Plaintiffs' trial exhibits will be identified with PTX numbers, starting with PTX-001. Plaintiffs' demonstratives will be identified with PDX numbers, starting with PDX 1. Exhibit 10 also contains Defendants' objections to Plaintiffs' trial exhibits, with a Key to the objection codes appended at the end of the exhibit.

- 63. Defendants' list of exhibits that they may offer at trial, except demonstrative exhibits and exhibits to be used solely for impeachment, and Plaintiffs' objections to Defendants' exhibits, are attached as **Exhibit 11**. Defendants' trial exhibits will be identified with DTX numbers, starting with DTX-001. Defendants' demonstratives will be identified with DDX numbers, starting with DDX 1. Exhibit 11 also contains Plaintiffs' objections to Defendants' trial exhibits, with a Key to the objection codes appended at the end of the exhibit.
- 64. The parties' list of joint exhibits that they may offer at trial are attached as **Exhibit 12**. The joint trial exhibits will be identified with JTX numbers, starting with JTX-001.
- 65. The parties agree that exhibits to be used solely for impeachment and/or cross-examination need not be included on the lists of trial exhibits or disclosed in advance of being used at trial.
- 66. This pretrial order contains the entire universe of exhibits to be used in any party's case-in-chief, as well as all objections to the admission of such objections (except for context-based objections to admissibility of any proposed exhibit, which the parties have agreed are reserved for trial), neither of which shall be supplemented without approval of all parties or leave of the Court, on good cause shown. Exhibits not listed will not be admitted unless good cause is shown.
- 67. No exhibit will be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. At some point before the completion of the witness' testimony, any party that has used an exhibit with the witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence, by exhibit number.
- 68. A party will provide exhibits to be used in connection with direct examination by 7:00 p.m. the night before their intended use, and objections will be provided no later than 9:00

p.m. the night before their intended use. The parties shall meet and confer by 10:00 p.m. the night before their intended use in order to resolve any objections. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its objections to the Court's attention prior to the witness being called to the witness stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

- 69. Exhibits not objected to will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided they are shown to a witness. Nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case. The parties agree that any description of a document on an exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the listed document or any other listed document.
- 70. All exhibits shall be deemed *prima facie* to be authentic, subject to the right of the party against whom the exhibit is introduced to adduce evidence to the contrary. The parties stipulate to the authenticity of all exhibits, except where specifically indicated with the specific reasons for the objection noted. Any objection to a document's authenticity must be made in this Pretrial Order, and must be established according to the Federal Rules of Evidence.
- Any party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to all evidentiary objections. Any exhibit, once admitted, may be used equally by each party, subject to any limitations as to its admission. The listing of a document on a party's exhibit list is not an admission that such document is relevant, or admissible, when offered by the opposing side for the purpose that the

opposing side wishes to admit the document. Each party reserves the right to object to the relevance of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

- 72. Legible copies of United States patents, file histories, and the contents of United States and foreign patents and translations thereof (if in English or translated into English) may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies.
- 73. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

B. <u>Demonstrative Exhibits</u>

- 74. The parties agree that the demonstrative exhibits that the parties intend to use at trial do not need to be included on their respective exhibit lists that are part of this Final Pretrial Order. Plaintiffs' demonstrative exhibits will be identified with PDX numbers, starting with PDX 1. Defendants' demonstrative exhibits will be identified with DDX numbers, starting at DDX 1.
- 75. The parties will exchange demonstratives to be used in opening statements by 7:00 p.m. the day before opening statements. The parties will provide any objections to such demonstratives by 9:00 p.m. on the day before opening statements. The parties shall meet and confer by 10:00 p.m. the night before their intended use in order to resolve any objections
- 76. A party will provide demonstrative exhibits to be used in connection with direct examination by 7:00 p.m. the night before their intended use, and objections will be provided no later than 9:00 p.m. the night before their intended use. The parties shall meet and confer by 10:00 p.m. the night before their intended use in order to resolve any objections. If any of the

demonstratives change after the deadline, the party intending to use the demonstrative will promptly notify the opposing party of the change(s).

- 77. The party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side in a viewable format. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as a PDF of 8.5 x 11 copies of the exhibits.
- 78. These provisions do not apply to demonstratives intended for use in closing statements, demonstratives created during testimony or demonstratives to be used for cross-examination, none of which need to be provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.
- 79. If good faith efforts to resolve objections to demonstrative exhibits fail, the objecting party shall bring its objections to the Court's attention prior to the opening statements or prior to the applicable witness being called to the witness stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

VII. DAMAGES

80. At present, Plaintiffs are not claiming damages. If Defendants launch their proposed generic bosutinib tablets prior to the Court's decision, the parties will promptly inform the Court.

VIII. BIFURCATED TRIAL

81. All issues will be tried without bifurcation.

IX. MOTIONS IN LIMINE

82. There are no *in limine* motions.

X. DISCOVERY

83. Discovery is completed.

XI. NUMBER OF JURORS

84. This is a non-jury trial.

XII. NON-JURY TRIAL

- 85. The parties request a detailed opinion from the Court post-trial.
- 86. The parties' propose the following post-trial briefing schedule:
 - The parties simultaneously exchange their opening post-trial briefs, limited to not more than 40 pages (or as set by the Court),, on November 25, 2019 (or as set by the Court).
 - The parties simultaneously exchange their responsive post-trial briefs, limited to not more than 40 pages (or as set by the Court), on December 16, 2019 (or as set by the Court).

XIII. LENGTH OF TRIAL

- 87. This case is currently scheduled for a **3-day** consolidated bench trial beginning on **November 4, 2019 at 8:30 a.m.** The parties proposed that each side receive **10.5 hours** for its trial presentations.
- 88. The trial will be timed. Unless otherwise ordered, time will be charged to a party for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, for playing its deposition designations and counter-designations, its argument on any motions for judgment as a matter of law, and all sides' argument on objections a party raises to another party's exhibits and demonstrative exhibits.

- 89. The Courtroom Deputy will keep a running total of trial time used by counsel. If any party uses all of its allotted trial time, the Court will terminate that party's trial presentation.
- 90. The parties request closing arguments to be heard on November 7th at 8:30 a.m., allotting 30 minutes for each party (60 minutes total) to present its closing argument. This time will not be charged as part of the 10.5 hours per side for trial presentation.

XIV. MOTIONS FOR JUDGMENT AS A MATTER OF LAW

91. The parties have agreed to the following procedure: The parties reserve the right to move pursuant to Fed. R. Civ. P. 52(c) for judgment on partial findings. The parties agree that either party making a motion pursuant to Fed. R. Civ. P. 52(c) will advise the Court of its motion promptly and in accordance fully with Fed. R. Civ. P. 52(c). If the Court requests more extensive argument on the motion, such argument will be taken up at the Court's first convenience. Supplementation of the motion in writing shall be made only upon request by the Court. Pursuant to Fed. R. Civ. P. 52(c), the Court may decline to render any judgment until the close of evidence.

XV. AMENDMENT OF THE PLEADINGS

92. The parties are not seeking amendments to the pleadings at this time.

XVI. ADDITIONAL MATTERS

A. Closing the Court to the Public

- 93. Plaintiffs contend that the Court should be open to the public for the entirety of the presentation of evidence at trial.
- 94. Sun requests the Court be closed to the public during the presentation of evidence relating to Sun's ANDA Product.

XVII. SETTLEMENT

95. The parties certify that they have engaged in a good faith effort to explore the resolution of this controversy by settlement and that no agreement has been reached. As of the filing date of this Order, parties are continuing to discuss settlement, but still intend to proceed to trial.

IT IS HEREBY ORDERED that this Final Pretrial Order shall control the subsequent course of the action unless modified by the Court to prevent manifest injustice.

DATED:	<u> </u>
	UNITED STATES DISTRICT JUDGE

APPROVED AS TO FORM AND SUBSTANCE

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/s/ Megan E. Dellinger /s/ Nathan R. Hoeschen

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